510(k) Summary

General Information

Manufacturer:	Gyrus ACMI, Inc. 136 Turnpike Rd. Southborough, MA 01772-2104
Establishment Registration Number:	3003790304
Contact Person:	Terrence E. Sullivan Executive Director, Regulatory Affairs
Date Prepared:	August 31, 2011

Device Description

Classification Name:	Bipolar endoscopic coagulator-cutter and accessories (21 CFR 884.4150), Class II Obstetrics and Gynecology Panel
Trade Name:	PKS™ (Plasmakinetic System) BiLL™ (Bipolar Laparoscopic Loop)
Generic/Common Name:	BiLap Loop / Bipolar Laparoscopic Loop

Predicate Devices

The predicate devices include:

1. LiNA Loop	K070315
2. Gyrus ACMI PlasmaCision Spatula	K041633
3. Gyrus ACMI G400 Workstation Generator (and 9-pin PKS™ PlasmaSpatula)	K050550

Indications for Use

The PKS™ (Plasmakinetic System) BiLL™ (Bipolar Laparoscopic Loop) instrument is a 5mm bipolar electrosurgical device. The device is intended to be used for the amputation/sectioning of the mobilised uterus during Laparoscopic Supracervical (Subtotal) Hysterectomy and the resection of devascularized subserosal pedunculated myomas. It is used in conjunction with the Gyrus ACMI G400 Workstation Generator.

Product Description

The Bipolar Laparoscopic Loop (PKS™ BiLL™) is a single use disposable high frequency RF bipolar accessory to be used in conjunction with the Gyrus ACMI G400 Workstation Generator. The PKS™ BiLL™ is a laparoscopic instrument. It is available in an 88mm x 215mm loop. The device is sterile for single use sterilized by gamma irradiation to an SAL of 10^{-6}.

Performance Data, Technological Features and Substantial Equivalence

The PKS™ BiLL™ utilizes features incorporated into the following legally marketed predicate devices:

- The bipolar PKS™ BiLL™ connects to the same electrosurgical generator, the Gyrus ACMI G400 Workstation Generator (K050550) as the predicate 9-pin PKS™ PlasmaSpatula (K050550).
- The PKS™ BiLL™ uses Bipolar PK technology and contains an identification capacitor embedded in the single use connector cable, which will be recognized by the generator to set default optimal power output parameters for the subject instrument, as does the PKS™ PlasmaSpatula (K050550)
- The mechanical design features of the PKS™ BiLL™ are similar to that of the predicate LiNA Loop (K070315).

The PKS™ BiLL™ has the same intended use as the predicates PKS™ PlasmaSpatula and LiNA Loop.

The PKS™ BiLL™ instrument is compliant to electrical standards specifically to those applicable sections of IEC 60601 incorporating electrical, thermal safety and Electromagnetic Interference.

The PKS™ BiLL™ instrument uses materials that are well established and used in other Gyrus ACMI FDA-cleared medical devices and the LiNA Loop. Full biocompatibility testing on all patient contacting parts has been performed in compliance to the relevant requirements of ISO-10993.

The PKS™ BiLL™ instrument is packaged and sterilized as a sterile single use device and tested to comply with ISO 11607 and ISO11137.

Preclinical testing has been undertaken to validate the mechanical design, usability considerations and software selection to provide the desired cut and user performance requirements. The performance was compared against the performance characteristics of the predicate LiNA Loop. Bench and preclinical testing demonstrated that the

performance requirements were met, and that the PKS™ BiLL™ exhibited comparable performance characteristics to the LiNA Loop.

Summary

The Gyrus ACMI Inc. Bipolar Laparoscopic Loop (PKS™ BiLL™), as described in this submission, is substantially equivalent to the predicates in intended use, materials, principles of operation and fundamental scientific technology and raises no new issues of safety and effectiveness. The evidence included within this submission supports the conclusion that the PKS™ BiLL™ instrument is substantially equivalent to the identified predicates and is safe and effective for its intended purpose.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Terrence E. Sullivan
Executive Director, Regulatory Affairs
Gyrus ACMI Inc.
136 Turnpike Road
SOUTHBOROUGH MA 01772

SEP - 1 2011

Re: K111059
Trade/Device Name: PKS™ (Plasmakinetic System) BiLL™ (Bipolar Laparoscopic Loop) instrument
Regulation Number: 21 CFR§ 884.4150
Regulation Name: Bipolar endoscopic coagulator-cutter and accessories
Regulatory Class: II
Product Code: HIN
Dated: August 17, 2011
Received: August 18, 2011

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K111059

Device Name: Gyrus ACMI® Bipolar Laparoscopic Loop (PKS™ BiLL™)

Statement of Intended use:

The PKS™ (Plasmakinetic System) BiLL™ (Bipolar Laparoscopic Loop) instrument is a 5mm bipolar electrosurgical device. The device is intended to be used for the amputation/sectioning of the mobilised uterus during Laparoscopic Supracervical (Subtotal) Hysterectomy and the resection of devascularized subserosal pedunculated myomas. It is used in conjunction with the Gyrus ACMI G400 Workstation Generator.

Prescription Use: __ **X** __ **OR** Over-the-Counter Use: _____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111059